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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,661	02/19/2004	Syed Rizvi	976	2178
40161, 7590 09/27/2007 DONALD A. KETTLESTRINGS 414 HUNGERFORD DRIVE SUITE 211 ROCKVILLE, MD 20850			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/780,661	Applicant(s) RIZVI, SYED	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/19/2004</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The receipt is acknowledged of applicant's IDS filed 02/19/2004.

Claims 1-10 are pending and included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "predominant amount" in claims 1 and 5 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 2, 4, 6 and 7 contain the trademark/trade name "octoxynol-9". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used

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properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe emulsifier and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5, 6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Compendium of Pharmaceutical Excipients for Vaginal Formulations" by Garg et al. by itself or combined with US 2002/0142690 ('690).

Garg et al. teach ideal vaginal formulation with desired characteristics in terms of safety, efficacy, patient compliance, aesthetic, acceptability to regulatory authorities, and cost requirements (page 14). Garg et al. teach towel to clean external vaginal area comprising lactic acid, water, potassium sorbate, O-9 (octoxynol-9), EDTA, cetylpyridinium chloride, and fragrance (page 17). Garg et al. further teach absorbent cotton in tampons as a carrier (top of page 18), and absorbent cotton tampon implies that it absorbs the composition applied to it to form impregnated substrate. Garg et al.

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teach amount of lactic acid is between 0.015-6.6%; amount of potassium sorbate is between 0.1-0.2%; amount of emulsifier can be as low as 0.3% for polyoxyethylene-polyoxypropylene copolymer, 0.5% for sodium lauryl sulfate, or 0.3-0.55 for cholesterol; amount of EDTA is between 0.01-0.1%; amount of preservative is between 0.01-0.02% (pages 18-22). Garg et al. teach alum potassium in the composition (page 18), claimed by applicant as odor absorbing agent.

Although Garg et al. teach all the ingredients of the product as instantly claimed, however, the reference does not explicitly teach the amount of the odor absorbing agent, or amount of antiseptic cetylpyridinium.

Garg et al. suggest the generic teaching of the amount of preservatives as low as 0.1-0.2% for benzoic acid that is known as antiseptic agent.

Although Garg et al. do not specifically teach the amounts some ingredients as claimed by applicant, however, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon impregnated with the composition

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disclosed by Garg et al., and optimize the amounts of different ingredients in order to achieve the desired anti-infective effect and mean while maintaining pleasant odor of the composition.

Although Garg et al. implies the composition is absorbed into a substrate, however, Garg et al. does not explicitly teach the impregnation of the composition in the absorbent article.

US '690 teaches substrate of web fabric impregnated with composition comprising octoxynol-9, and deliver impregnated material upon wiping the contaminated surface, and avoid re-positioning the contaminant upon the surface which is being cleaned (abstract; paragraphs: 0023, 0025, 0029, 0031). The wipes can be handled safely, non-toxic, and even if misplaced poses little or no risk to the end user, and far more effective at removing stubborn embarrassing contaminants helping preventing sexually transmitted diseases (paragraph 0034).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon comprising the composition disclosed by Garg et al., and optimize the amounts of different ingredients to obtain specific desired effect such as anti-infective effect, and further apply the composition to the towel or tampon by impregnation as disclosed by US '690, motivated by the teaching of US '690 that wipes impregnated with anti-infective composition can be handled safely, and even if misplaced poses little or no risk to the end user, and far more effective at removing stubborn embarrassing contaminants helping preventing sexually transmitted diseases, with reasonable expectation of treating vaginal

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contamination safely and effectively with reduction of the risk of transmitting sexually transmitted diseases using substrate impregnated with the composition disclosed by Garg et al.

5. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garg et al., or over the combination of Garg et al. and US '690, and further in view of the article "Natural Deodorant" by Carrubba Inc.

The article "Natural Deodorant" by Carrubba Inc. was available before 11/13/2001, the date it was faxed to applicant. This implies that the article was available before that date 11/13/2001.

The teaching of Garg et al. by itself or combined with US '690 are discussed above. The teachings suggest all the ingredients in almost the claimed amounts.

However, Garg et al. by itself or combined with US '690 do not teach saccharomyces ferment as claimed by claims 4 and 7.

The article by Carrubba Inc. teaches saccharomyces ferment used as personal deodorant for feminine hygiene. The product is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic (first page).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon impregnated with composition comprising the ingredients disclosed by Garg et al. by itself or combined with US '690, and replace the fragrance element from the composition with saccharomyces ferment disclosed by Carrubba Inc., motivated by the teaching of the Carrubba article that

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saccharomyces ferment is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic, with reasonable expectation of having substrate to be used on the genitalia impregnated with composition disclosed by Garg et al., and further comprising saccharomyces ferment that is deodorant for feminine hygiene articles and further is non-toxic, non-irritating, and non-allergenic that effectively, safely and pleasantly disinfect the site of wiping.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

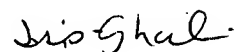
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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

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ISIS GHALI
PRIMARY EXAMINER